Regulatory submission query form for human medicines

This form should be used when advice on a human regulatory submission is required and where the published guidance does not offer sufficient information on the topic. The query should concern issues with Module 1 of the eCTD submission documentation for human medicines.

The completed form should be submitted as a Microsoft Word document to facilitate the inclusion of the response. Please send the completed form to submissions@hpra.ie. The target response time for queries submitted with this form is two weeks from the date of receipt of the form.

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| 1. Contact and product details

Contact name and position      Company and address      Contact telephone number      Contact email address      Product name and INN      PA number       |

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| 1. previous correspondence

Previous HPRA assessment case number (if relevant):     Previous HPRA correspondence in relation to the query (add attachments if relevant):      |

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| 1. query

Relevant background information to the query:     Specific query:      |

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| 1. HPRA RESPONSE

     Date of response:      *Note: The HPRA response is based solely on the information provided in this form.* |